DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

93508d

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WARNING LETTER
NWE-32-02W

VIA FEDERAL EXPRESS

September 12, 2002

Rita Battles
President
University of Massachusetts Memorial Medical Center
University Campus
55 Lake Avenue North
Worcester, MA 01655

Dear Ms. Battles:

On August 1-8, 2002, representatives of the Food and Drug Administration (FDA) inspected the unlicensed blood bank located at the University of Massachusetts Memorial Medical Center, University Campus, in Worcester, Massachusetts. As explained in the FDA Form 483 given to representatives of your facility at the end of the inspection, the investigators documented significant violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 351(a)(2)(B), and FDA implementing regulations. FDA acknowledges the letter dated August 21, 2002, from Richard H. Seder, M.D., addressing the observations listed on the Form 483. Dr. Seder's response does not fully address the violations observed during the inspection.

1. Your facility failed to have available a record from which unsuitable donors could be identified so that products from such individuals would not be distributed, as required by 21 C.F.R. § 606.160(e). Specifically:

   a. On [redacted] you collected unit [redacted] from donor [redacted] This donor tested positive for HCV Antibody, HCV RIBA, and NAT HCV. According to your own procedure, SOP 5.8.4, "Procedure for Deferral or Re-Entry of Blood Donors Who Tested Positive for Infectious Disease Markers," this donor should have been listed as "INACTIVE," signifying permanent deferral. During the inspection, the investigators observed that your records identified this donor as "ACTIVE."

b. On [redacted] you collected unit [redacted] from donor [redacted] This donor tested positive for STS and HBc and was reactive for FTA. According to SOP 5.8.4, this donor should have been listed as "INACTIVE," signifying permanent deferral. During the inspection, the investigators observed that your records identified this donor as "TEMP DEFER."

2. Your facility failed to prepare the skin of the donor at the site of phlebotomy thoroughly and carefully by a method that gives maximum assurance of a sterile container of blood, as required by 21 C.F.R. § 640.4(f). Specifically, on August 1, 2002, the investigators observed in the collection of unit [redacted] that the scrub of the phlebotomy site lasted less than 10 seconds and that after the scrub, the nurse wiped the area from outside of the iodine scrub through the prepared site. This is contrary to your own SOP 5.6, which calls for a 30 second scrub and states, "NEVER GO BACK TOWARD THE CENTER."

3. Your facility's records were not as detailed as necessary to provide a complete history of the work performed, as required by 21 C.F.R. § 606.160. Specifically, on August 1, 2002, a donor had a "yes" response to question 14 regarding CJD. The donor was, therefore, not asked questions 15-32. The answers to these questions were nevertheless entered into the computer as "no." Similarly, on [redacted] you collected unit [redacted] from donor [redacted] Our investigators observed that your records state that this donor had never before donated. In fact, the donor had donated at least six units before. The donor tested positive for HBc.

This letter is not intended to be an all-inclusive list of deficiencies at your blood bank facility. As president of the University of Massachusetts Memorial Medical Center, University Campus, you are responsible for ensuring that the collection and distribution of blood and blood components by your facility comply with the Act and with FDA regulations.

In no more than fifteen (15) working days of receiving this letter, please notify this office in writing of the specific steps you have taken to correct these violations and to prevent them from recurring. Your response should also indicate the status of the modifications you have requested to the Meditech software program you are using, advise us as to the hiring status of the new Quality Assurance/Compliance Specialist and describe that employee's proposed duties, provide copies of your revised SOPs and your plan for implementing these procedures to assure that all personnel are familiar with them. In addition, please provide assurances that adequate standard operating procedures exist for all of your blood banking operations. Your response should also include examples of documentation showing that corrections have been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time period within which corrections will be completed. Failure to correct these violations promptly could result in further action being taken by FDA, including seizure and/or injunction.

Please submit your response to Karen N. Archdeacon, Compliance Officer, New England District Office, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely yours,

Gail T. Costello
New England
District Director

cc:

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